



ATTORNEY'S DOCKET NUMBER: 2003080-0138 (SK-744-CON8)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Danishefsky *et al.* Examiner: Solola, T. A.  
Serial No.: 10/695,582 Art Unit: 1626  
Filed: October 28, 2003  
For: SYNTHESIS OF EPOTHILONES, INTERMEDIATES THERETO,  
ANALOGUES AND USES THEREOF

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**STATEMENT UNDER 37 C.F.R. §§ 1.56, 1.97, & 1.98**

Pursuant to the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☐ An *original* Information Disclosure Statement; or  
☒ A *supplemental* Information Disclosure Statement.

**Certificate of Mailing**

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as Express Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

November 30, 2004

Date

Signature

Kenneth R. Maben

Typed or Printed Name of person signing certificate

12/03/2004 MBLANCO 00000002 031721 10695582  
02 FC:1806 180.00 DA

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☐ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
  - ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☐ Before the mailing of a first Office action on the merits; or
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☒ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
  - ☐ Certifies that *either*:
    - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
    - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☒ Includes herewith the fee set forth in § 1.17(p). Please charge Deposit Account No. 03-1721.

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

☐ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

☒ A copy of each cited reference not indicated with an asterisk is included;

☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

☐ Does not contain non-English language citations;

☒ Does contain non-English language citations, for which an English language abstract is submitted.

[ ] Does contain non-English language citations which were cited on an International Search Report (a copy of which is enclosed herewith).

[ ] Includes one or more translations of a non-English citation.

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,



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Date: November 30, 2004

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FORM PTO-1449

(REV. 8-83)

U.S. Department of  
Commerce  
Patent and Trademark OfficeATTY. DOCKET:  
2003080-0138  
(SK-744-CON8)IN RE  
APPLICATION NO.  
10/695,582:

## INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

APPLICANT: Danishefsky *et al*FILING DATE:  
October 28, 2003

GROUP: 1626

## U.S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	5,021,430	Ksander, <i>et al.</i>	June 4, 1991	514	332
	5,917,084	Jiang, <i>et al.</i>	June 29, 1999	560	174
	5,969,145	Schinzer, <i>et al.</i>	October 19, 1999	548	110
	6,043,372	Schinzer, <i>et al.</i>	March 28, 2000	548	110
	6,156,905	Schinzer <i>et al.</i>	December 5, 2000	548	204
	6,204,388	Danishefsky <i>et al.</i>	March 20, 2001	546	340
	6,242,469	Danishefsky <i>et al.</i>	June 5, 2001	514	365
	6,262,094	Höfle, <i>et al.</i>	July 17, 2001	514	365
	6,284,781	Danishefsky, <i>et al.</i>	September 4, 2001	514	365
	6,288,237	Höfle, <i>et al.</i>	September 11, 2001	548	203
	6,291,684	Borzilleri, <i>et al.</i>	September 18, 2001	548	961
	6,300,355	Danishefsky, <i>et al.</i>	October 9, 2001	514	374
	6,302,838	O'Reilly <i>et al</i>	October 16, 2001	574	365
	6,303,342	Julien	October 16, 2001	435	76
	6,303,767	Betlach	October 16, 2001	536	23.2
	6,316,630	Danishefsky <i>et al.</i>	November 13, 2001	546	281.7
	6,320,045	Kim, <i>et al.</i>	November 20, 2001	540	463
	6,350,878	Altmann, <i>et al.</i>	February 26, 2002	548	110
	6,359,140	Höfle, <i>et al.</i>	March 19, 2002	548	204
	6,365,749	Kim <i>et al.</i>	April 2, 2002	548	204
	6,369,234	Danishefsky <i>et al.</i>	April 9, 2002	548	204
	6,380,227	Mutz	April 30, 2002	514	365
	6,380,394	Nicolaou	April 20, 2002	548	125
	6,380,395	Vite	April 30, 2002	548	146
	6,383,787	Schupp	May 7, 2002	435	183
	6,384,230	Mulzer	May 7, 2002	548	203
	6,387,927	Altmann	May 14, 2002	514	311
	6,399,638	Vite	June 4, 2002	514	366
	6,410,301	Julien	June 25, 2002	435	252.3
	6,419,692	Yang <i>et al.</i>	July 16, 2002	623	115
	6,441,186	Nicolaou <i>et al.</i>	August 27, 2002	548	204

<b>FORM PTO-1449</b> <b>(REV. 8-83)</b>		U.S. Department of Commerce Patent and Trademark Office		ATTY. DOCKET: 2003080-0138 (SK-744-CON8)		IN RE APPLICATION NO. 10/695,582:	
<b>INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)				APPLICANT: Danishefsky <i>et al</i>			
				FILING DATE: October 28, 2003		GROUP: 1626	
	6,457,303	Georg <i>et al.</i>	October 1, 2002	56	465		
	6,625,666	O'Reilly <i>et al.</i>	October 21, 2003	710	5		
	6,780,620	Li <i>et al.</i>	August 24, 2004	435	117		
	6,800,653	Regueiro-Ren <i>et al.</i>	October 5, 2004	514	365		
<b>U.S. PATENT APPLICATIONS</b>							
Examiner's Initials:	Serial Number:	Applicant:	Publication Date:	Group:	Art Unit:		
	2001/0031880	Borzilleri <i>et al.</i>	October 18, 2001				
	2001/0034452	Hoefle <i>et al.</i>	April 16, 2001				
	2001/0051356	Khosla	December 13, 2001				
	2002/0002162	Lee	January 3, 2002				
	2002/0002194	Danishefsky <i>et al.</i>	January 3, 2002				
	2002/0004229	Santi <i>et al.</i>	January 10, 2002				
	2002/0010328	Reeves <i>et al.</i>	January 24, 2002				
	2002/0028839	O'Reilly <i>et al.</i>	March 7, 2002				
	2002/0042109	Vite <i>et al.</i>	April 11, 2002				
	2002/0045220	Khosla <i>et al.</i>	April 18, 2002				
	2002/0045609	Ashley <i>et al.</i>	April 18, 2002				
	2002/0052028	Santi <i>et al.</i>	May 2, 2002				
	2002/0062030	White <i>et al.</i>	May 23, 2002				
	2002/0065295	Chu <i>et al.</i>	May 30, 2002				
	2002/0143038	Bandyopadhyay <i>et al.</i>	October 3, 2002				
	2003/0203938	Nicolaou <i>et al.</i>	October 30, 2003				
	2003/0203929	Ghosh	October 30, 2003				
	2003/0203876	Hoogevest	October 30, 2003				
	2003/0194787	Hofmann <i>et al</i>	October 16, 2003				
	2004/0170752	Luthra <i>et al.</i>	September 2, 2004				
	2004/0172121	Eidenschink <i>et al.</i>	September 2, 2004				
	2004/0172127	Kantor	September 2, 2004				
	2004/0171562	Trouet <i>et al.</i>	September 2, 2004				



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<b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>					APPLICANT: Danishefsky <i>et al</i>			
					FILING DATE: October 28, 2003		GROUP: 1626	
	2004/0185053	Govindan	September 23, 2004					
	2004/0198638	Li <i>et al.</i>	October 7, 2004					
	20004/0209942	Li	October 21, 2004					
	2004/0023345	Vite <i>et al.</i>	February 5, 2004					
	2004/0024032	Voi <i>et al.</i>	February 5, 2004					
	2004/0024033	O'Reilly <i>et al.</i>	February 5, 2004					
	2004/0030147	White <i>et al.</i>	February 12, 2004					
	2004/0038324	Atadja <i>et al.</i>	February 26, 2004					
	2004/0039026	Nicolaou <i>et al.</i>	February 26, 2004					
	2004/0044203	Wittman <i>et al.</i>	March 4, 2004					
	2004/0044221	Danishefsky <i>et al.</i>	March 4, 2004					
	2004/0049051	Hoefle <i>et al.</i>	March 11, 2004					
	2004/0053910	Danishefsky <i>et al.</i>	March 18, 2004					
	2004/0053978	Lee <i>et al.</i>	March 18, 2004					
	2004/0053995	Danishefsky <i>et al.</i>	March 18, 2004					
	2004/0054186	Das <i>et al.</i>	March 18, 2004					
	2004/0054188	Kusters <i>et al.</i>	March 18, 2004					
	2004/0058899	Klimko	March 25, 2004					
	2004/0058969	Buchmann <i>et al.</i>	March 25, 2004					
	2004/0062810	Hunter <i>et al.</i>	April 1, 2004					
	2004/0063707	Bhide <i>et al.</i>	April 1, 2004					
	2004/0063708	Bhide <i>et al.</i>	April 1, 2004					
	2004/0063712	Salvati <i>et al.</i>	April 1, 2004					
	2004/0063715	Paruch <i>et al.</i>	April 1, 2004					
	2004/0072760	Carboni <i>et al.</i>	April 15, 2004					
	2004/0072832	Bhide <i>et al.</i>	April 15, 2004					
	2004/0072835	Paruch <i>et al.</i>	April 15, 2004					
	2004/0072870	Nicolaou <i>et al.</i>	April 15, 2004					
	2004/0072882	Johnson <i>et al.</i>	April 15, 2004					
	2004/0073026	Das <i>et al.</i>	April 15, 2004					

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				FILING DATE: October 28, 2003		GROUP: 1626	
	2004/0076672	Hunter <i>et al.</i>	April 22, 2004				
	2004/0077696	Borzilleri <i>et al.</i>	April 22, 2004				
	2004/0077875	Das <i>et al.</i>	April 22, 2004				
	2004/0082651	Wessjohann <i>et al.</i>	April 29, 2004				
	2004/0087610	Pardee <i>et al.</i>	May 6, 2004				
	2004/0087634	Hoefle <i>et al.</i>	May 6, 2004				
	2004/0092478	Rothermel <i>et al.</i>	May 13, 2004				
	2004/0092514	Velaparthi <i>et al.</i>	May 13, 2004				
	2004/0092560	Hoefle <i>et al.</i>	May 13, 2004				
	2004/0097516	Dwyer <i>et al.</i>	May 20, 2004				
	2004/0097517	Dwyer <i>et al.</i>	May 20, 2004				
	2004/0102451	Guzi <i>et al.</i>	May 27, 2004				
	2004/0102452	Guzi <i>et al.</i>	May 27, 2004				
	2004/0102495	Danishefsky <i>et al.</i>	May 27, 2004				
	2004/0106624	Guzi <i>et al.</i>	June 3, 2004				
	2004/0106985	Jang	June 3, 2004				
	2004/0116442	Guzi <i>et al.</i>	June 17, 2004				
	2004/0126379	Adolf <i>et al.</i>	July 1, 2004				
	2004/0127432	Nicolaou <i>et al.</i>	July 1, 2004				
	2004/0132146	Benigni <i>et al.</i>	July 8, 2004				
	2004/0133271	Jang	July 8, 2004				
	2004/0132692	Sherrill <i>et al.</i>	July 8, 2004				
	2004/0132736	Guzi <i>et al.</i>	July 8, 2004				
	2004/0132754	Brandt <i>et al.</i>	July 8, 2004				
	2004/0142931	Vite <i>et al.</i>	July 22, 2004				
	2004/0142990	Hofmann <i>et al.</i>	July 22, 2004				
	2004/0152708	Li <i>et al.</i>	August 5, 2004				
	2004/0157897	DiMarco <i>et al.</i>	August 12, 2004				
	2004/0167083	Bosslet <i>et al.</i>	August 26, 2004				
	2004/0167097	Zhou <i>et al.</i>	August 26, 2004				

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<b>INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)				APPLICANT: Danishefsky <i>et al</i>			
				FILING DATE: October 28, 2003		GROUP: 1626	
	2004/0176429	Li <i>et al.</i>		September 9, 2004			
	2004/0192621	Nihei <i>et al.</i>		September 30, 2004			
<b>FOREIGN PATENT DOCUMENTS</b>							
Examiner's Initials	Document No.	Country	Date	Translation			
				Yes	No		
	DE 195 42 986.9	Germany	17 November 1995				
	DE 196 45 361	Germany	30 April 1998				
	DE 196 45 362	Germany	30 April 1998				
	DE 199 08 760	Germany	24 August 2000				
	EP 1 440 973	Europe	July 28, 2004				
	EP 1 428 826	Europe	June 16, 2004				
	EP 1 407 784	Europe	April 14, 2004				
	EP 1 386 922	Europe	February 4, 2004				
	EP 1 080 082	Europe	October 6, 2004				
	EP 1 043 369	Europe	October 11, 2000				
	WO 04/087673	International	October 14, 2004				
	WO 04/087045	International	October 14, 2004				
	WO 04/085421	International	October 7, 2004				
	WO 04/084909	International	October 7, 2004				
	WO04/081196	International	September 23, 2004				
	WO 04/080458	International	September 23, 2004				
	WO 04/078994	International	September 16, 2004				
	WO 04/078978	International	September 16, 2004				
	WO 04/075943	International	September 10, 2004				
	WO 04/073656	International	September 2, 2004				
	WO 04/072003	International	August 26, 2004				
	WO 04/069224	International	August 19, 2004				
	WO 04/063151	International	July 29, 2004				
	WO 04/061116	International	July 22, 2004				

<b>FORM PTO-1449</b> <b>(REV. 8-83)</b>		U.S. Department of Commerce Patent and Trademark Office		ATTY. DOCKET: 2003080-0138 (SK-744-CON8)		IN RE APPLICATION NO. 10/695,582:	
<b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>				APPLICANT: Danishefsky <i>et al</i>			
				FILING DATE: October 28, 2003		GROUP: 1626	
	WO 04/056832	International	July 8, 2004				
	WO 04/054624	International	July 1, 2004				
	WO 04/054622	International	July 1, 2004				
	WO 04/054514	International	July 1, 2004				
	WO 04/052401	International	June 24, 2004				
	WO 04/052361	International	June 24, 2004				
	WO 04/052237	International	June 24, 2004				
	WO 04/050089	International	June 17, 2004				
	WO 04/050057	International	June 17, 2004				
	WO 04/048372	International	June 10, 2004				
	WO 04/043954	International	May 27, 2004				
	WO 04/043454	International	May 27, 2004				
	WO 04/043400	International	May 27, 2004				
	WO 04/043363	International	May 27, 2004				
	WO 04/035050	International	April 29, 2004				
	WO 04/032923	International	April 22, 2004				
	WO 04/032872	International	April 22, 2004				
	WO 04/032866	International	April 22, 2004				
	WO 04/030627	International	April 15, 2004				
	WO 04/030620	International	April 15, 2004				
	WO 04/028610	International	April 8, 2004				
	WO 04/028582	International	April 8, 2004				
	WO 04/025254	International	April 1, 2004				
	WO 04/026877	International	April 1, 2004				
	WO 04/026872	International	April 1, 2004				
	WO 04/026867	International	April 1, 2004				
	WO 04/026310	International	April 1, 2004				
	WO 04/026229	International	April 1, 2004				
	WO 04/024735	International	March 25, 2004				
	WO 04/022560	International	March 18, 2004				

<b>FORM PTO-1449</b> <b>(REV. 8-83)</b>		U.S. Department of Commerce Patent and Trademark Office		ATTY. DOCKET: 2003080-0138 (SK-744-CON8)		IN RE APPLICATION NO. 10/695,582:	
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				FILING DATE: October 28, 2003		GROUP: 1626	
	WO 04/022559	International	March 18, 2004				
	WO 04/022080	International	March 18, 2004				
	WO 04/022062	International	March 18, 2004				
	WO 04/018635	International	March 4, 2004				
	WO 04/018478	International	March 4, 2004				
	WO 04/018000	International	March 4, 2004				
	WO 04/017943	International	March 4, 2004				
	WO 04/016269	International	February 26, 2004				
	WO 04/014919	International	February 19, 2004				
	WO 04/012735	International	February 12, 2004				
	WO 04/007476	International	January 22, 2004				
	WO 03/096975	International	November 27, 2003				
	WO 03/022844	International	March 20, 2003				
	WO 02/098868	International	14 May 2002				
	WO 02/096281	International	December 5, 2004				
	WO 02/080846	International	17 October 2002				
	WO 02/072858	International	27 February 2002				
	WO 02/072085	International	19 September 2002				
	WO 02/067941	International	06 September 2002				
	WO 02/066038	International	06 February 2002				
	WO 02/066033	International	29 August 2002				
	WO 02/062338	International	15 August 2002				
	WO 02/060904	International	08 August 2002				
	WO 02/058701	International	01 August 2002				
	WO 02/058700	International	01 August 2002				
	WO 02/058699	International	01 August 2002				
	WO 99/028324	International	10 June 1999				
	WO 99/027890	International	10 June 1999				
	WO 99/007692	International	18 February 1999				
	WO 99/003848	International	28 January 1999				

FORM PTO-1449 (REV. 8-83)		U.S. Department of Commerce Patent and Trademark Office		ATTY. DOCKET: 2003080-0138 (SK-744-CON8)		IN RE APPLICATION NO. 10/695,582:	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT: Danishefsky <i>et al</i>			
				FILING DATE: October 28, 2003		GROUP: 1626	
	WO 99/002514	International		21 January 1999			
	WO 99/001124	International		14 January 1999			
	WO 98/038192	International		3 September 1998			
	WO 98/022461	International		28 May 1998			
	WO 98/008849	International		5 March 1998			
	WO 97/019086	International		29 May 1997			
	WO 95/003035	International		2 February 1995			
	WO 93/010121	International		27 May 1993			
Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)						
	Agrawal, et al., "Treatment of Recurrent Cervical Adenocarcinoma with BMS-247550, an Epothilone B Analog", <i>Gynecologic Oncology</i> , <b>90</b> : 96-99, 2003.						
	Altaha, et al., "Epothilones: A Novel Class of Non-Taxane Microtubule-Stabilizing Agents", <i>Current Pharmaceutical Design</i> , <b>8</b> : 1707-1712, 2002.						
	Altmann <i>et al.</i> , "Epothilone B and Its Analogs –A New Family of Anticancer Agents" <i>Mini-Rev. Med. Chem.</i> <b>3</b> :149-158, 2003.						
	Baggiolini <i>et al.</i> , "Stereocontrolled Total Synthesis of 1 $\alpha$ , 25-Dihydroxycholecalciferol and 1 $\alpha$ , 25-Dihydroxyergocalciferol" <i>J. Org. Chem.</i> <b>51</b> :3098-3108, 1986.						
	Balog <i>et al.</i> , "Stereoselective Syntheses and Evaluation of Compounds in the 8-Desmethylepothilone A Series: Some Surprising Observations Regarding Their Chemical and Biological Properties." <i>Tet. Lett.</i> <b>38</b> (26): 4529-4532 (1997).						
	Bayes, et al., "Gateways to Clinical Trials", <i>Methods Find Exp. Clin. Pharmacol</i> , <b>25</b> (1): 53-76, 2003.						
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